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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/014,774	10/29/2001	Alessandra D'Azzo	2427/1F509-US1	9922
29311	7590	12/02/2003	EXAMINER	
DARBY & DARBY P.O. BOX 5257 NEW YORK, NY 10150-5257			FRONDA, CHRISTIAN L	
			ART UNIT	PAPER NUMBER
			1632	

DATE MAILED: 12/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	10/014,774	D'AZZO ET AL.
	Examiner Christian L Fronda	Art Unit 1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM
 THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on _____.
 2a) This action is **FINAL**. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-33 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
 5) Claim(s) ____ is/are allowed.
 6) Claim(s) ____ is/are rejected.
 7) Claim(s) ____ is/are objected to.
 8) Claim(s) 1-33 are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on ____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.
 13) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
 a) The translation of the foreign language provisional application has been received.
 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- | | |
|--|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ . | 6) <input type="checkbox"/> Other: _____ . |

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DETAILED ACTION***Election/Restriction***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-8, drawn to an isolated Ozz protein, classified in class 530, subclass 350.
 - II. Claims 9-17 and 19-21, drawn to an isolated nucleic acid encoding an Ozz protein, a vector, a host cell, a method of producing an Ozz protein, classified in class 435, subclass 69.1.
 - III. Claim 18, drawn to a non-human animal transformed with a vector that comprises a nucleic acid encoding a fragment of an Ozz protein, classified in class 800, subclass 8.
 - IV. Claims 22 and 23, drawn to a OZZ muscle-specific promoter, classified in class 536, subclass 24.1.
 - V. Claim 24, drawn to an antibody, classified in class 530, subclass 387.1.
 - VI. Claim 25, drawn to a method for detecting an Ozz protein using an antibody to the Ozz protein, classified in class 435, subclass 7.1.
 - VII. Claims 26-28, drawn to a method for detecting expression of Ozz mRNA by hybridizing to an Ozz-specific nucleic acid, classified in class 435, subclass 6.
 - VIII. Claims 29 and 30, drawn to a method for detecting damage to muscle tissue comprising detecting an increase in the level of Ozz protein in a blood or a blood fraction, classified in class 435, subclass 4.
 - IX. Claims 31-33, drawn to a method for detecting a disease associated with a defect in Ozz expression in a subject, classified in class 435, subclass 4.

2. The inventions are distinct, each from the other because of the following reasons:

Inventions of Groups I-V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Each of the products of Groups I-V are independent chemical entities and require different literature searches.

The inventions of Groups V-IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The processes of Groups V-IX are distinct both physically and functionally; require different process steps, reagents, and parameters; have different purposes; and produce different products.

The invention of Groups I, III, IV, and V are unrelated to the inventions of Groups VI-IX. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together

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and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The processes of Groups VI-IX do not require the products of Groups I, III, IV, and V.

The invention of Groups I-IV are unrelated to the inventions of Groups VI and VIII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The processes of Groups VI and VIII do not require the products of Groups I-IV.

The invention of Groups I and III-V are unrelated to the inventions of Groups VII and IX. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The processes of Groups VII and IX do not require the products of Groups I and III-V.

The invention of Group V is related to the inventions of Groups VI and VIII as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process of using that product such as using the antibody in a process for purifying and isolating the Ozz protein from a biological source.

The invention of Group II is related to the inventions of Groups VII and IX as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process of using that product such as using the nucleic acid in a recombinant process for making the Ozz protein.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

3. The claims are generic to a plurality of disclosed patentably distinct polynucleotide and polypeptide sequences.

If any Group is elected, then Applicants must elect one sequence selected from the group consisting of SEQ ID NOS: 1-5, 7, 9, 11, 19, and 21-24 for examination.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed sequence, even

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though this requirement is traversed. Should applicant traverse on the ground that the sequences are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the sequences to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

4. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L. Fronda whose telephone number is (703)305-1252. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (703)308-3804. The fax phone number for this Group is (703)308-0294. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703)308-0196.

CLF



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